California Bar Association
2005 Winter Section Education Institute

Medicare Reforms, Prescription Drugs and Importation

Health Law Committee Presentation

January 28, 2005

Medicare Reforms, Prescription Drugs and Importation

Agenda:

Prescription drug benefit

Medicare Reforms: *The 2003 Medicare Modernization Act*

- Politics and promises: is there a problem, and does the MMA fix it?
- The devilish details: Drug discounts and the new prescription drug benefit for seniors
- Medical savings accounts

Importation: Drugs from Canada and elsewhere

- The federal approach: “someday, maybe”
- California’s position(s), responses and prospects

Medicare Program

- MEDICARE is the federal healthcare program for the elderly and disabled and those with end-stage renal disease
  - Enacted in 1965 and amended many times since then
  - Continual concern has been the increasing cost of the program
  - Also there are gaps in Medicare coverage compared to typical private insurance – most notably lack of coverage of outpatient prescription drugs

- MEDICAID is the state-federal program for low-income individuals

Recent Legislation

- In December 2003, new Medicare legislation enacted – “Medicare Prescription Drug, Improvement, and Modernization Act of 2003”
- Two major intended purposes:
  - Adding coverage of outpatient prescription drugs
  - Reforming the Medicare program to look more like private insurance programs in the hope that this will lead to more control over the increasing costs

2003 Medicare Legislation

- Provisions of particular interest
  - Drug discount card
  - New Medicare benefit for outpatient prescription drugs
  - Importing drugs from Canada

MEDICARE DISCOUNT CARDS

Medicare-Endorsed
Prescription Drug Discount Cards

- "Medicare endorsed" discount cards became available to Medicare beneficiaries on June 1, 2004
- This is a 1½ year program (through 2005)
- All Medicare beneficiaries are eligible for Medicare-endorsed discount cards except those with Medicaid coverage
  - "Medically needy" Medicaid beneficiaries are eligible

Discount Card Programs

- Cards are being offered by various drug store chains, insurance companies, etc.
  - 27 cards available nationally to the general Medicare population
  - other regional cards
  - additional cards available to enrollees in Medicare Advantage (HMO) plans

Discount Cards

- To receive the discounts, individuals were required to select a discount card and enroll in the plan by May 2004
- An individual can be enrolled in only one card at a time – may change enrollment for 2005 at the end of 2004
- Discount card may charge enrollment fee of up to $30 per year
  - 5 cards are being offered for free

Discounts Will Vary

- Discounts on particular drugs vary from card to card
- Card issuers negotiate with drug manufacturers for discounts
- Medicare beneficiaries should select a card based on the discounts available for the most costly drugs they use (and on the enrollment fee)
- Medicare offers comparisons between cards
  - On Medicare web site: www.medicare.gov
  - Can also call 1-800-MEDICARE

Payment Assistance

- Low-income beneficiaries without Medicaid or other drug coverage can receive money to spend on prescription drugs
  - $600 in 2005
  - Unused portion in 2004 rolled over to 2005
  - Government pays for card enrollment fee
  - Beneficiaries receiving financial assistance would still be responsible for 5-10% of cost

Was a discount card a good investment?

- California's pre-existing discount deal for Medicare seniors
- California HealthCare Foundation Study: "Medicare Discount Drug Card Savings in California: Technical Summary"

The California Experience

- The Medicare Drug Discount Program and California's Existing Drug Discount Program for Medicare Recipients

Existing Discount

- Senate Bill 393 (Speier) (Ch.946; Stats. 1999)
- As a condition of a pharmacy's participation in the Medi-Cal program the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, must charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines.

Ask and Ye Shall Receive

- To obtain Medi-Cal rates, a Medicare participant must (1) Obtain their prescription drugs through a Medi-Cal participating pharmacy;(2) Present their Medicare card; and(3) Ask for Medi-Cal prices for their prescription. No means test – Medi-Cal rates available regardless of the consumer's income.

Sweet Savings

- As a result of receiving Medi-Cal rates, California's Medicare population saves an average of 20% on pharmacy retail prices.
- No need to purchase a discount card results in additional savings.

The CHCF Study

- Report by the California HealthCare Foundation published June 2004 (see handout)
- Consumers Union researched the impact of the Medicare pharmacy discount by analyzing the cost of 34 commonly prescribed drugs that make up almost 50% of drugs prescribed for the Medicare population.

Show Me the … $aving$

- Result of Study: Many, but not all Medicare approved discount cards provide additional savings.
- Using Medi-Cal rates as the benchmark, Californians may actually pay more for prescription drugs under the Medicare Discount Drug Program.

Pay more, save more

- Benefits most likely to be gained from participating in Medicare Discount Drug Program if the consumer spends more than $1000 per year for prescriptions and does not have other source of prescription coverage benefits.

Not All Discount Plans Are Created Equally

- If a Medicare beneficiary has coverage through a Medicare supplemental policy (a Medi-gap policy) the savings realized through the Medicare discount drug program are decreased. Study showed savings ranged from 10% to an actual increase in cost by 6%

An Alternative to Government Sponsored Discount Plans

- The CHCF Study also compared prices of prescription drugs at Costco. Costco prices were similar to Medi-Cal rates (and think of how many other things can be purchased at Costco; it is amazing how much you can save if you spend enough!)

MEDICARE PRESCRIPTION DRUG BENEFIT

New Prescription Drug Benefit

- Currently Medicare covers drugs administered in hospitals and physician offices but only a few oral drugs

- New drug benefit, effective January 1, 2006, will cover oral and self-injected drugs

Voluntary Benefit

- Voluntary benefit – Medicare beneficiaries do not have to enroll in the new drug benefit
- Factors to consider:
  - Premium paid by beneficiary – estimated to be $35 per month in 2006 (rising to $58 in 2013)
  - Only partial coverage of drugs
  - Individuals with good retiree insurance may not have a need for the new benefit

Privately Administered

- Drug coverage will be available only in two ways
  - Enrollment in a Medicare Advantage plan (HMO or PPO) that offers drug coverage
  - Enrollment in a private insurance plan that offers only Medicare drug coverage

- Government subsidizes the private plans

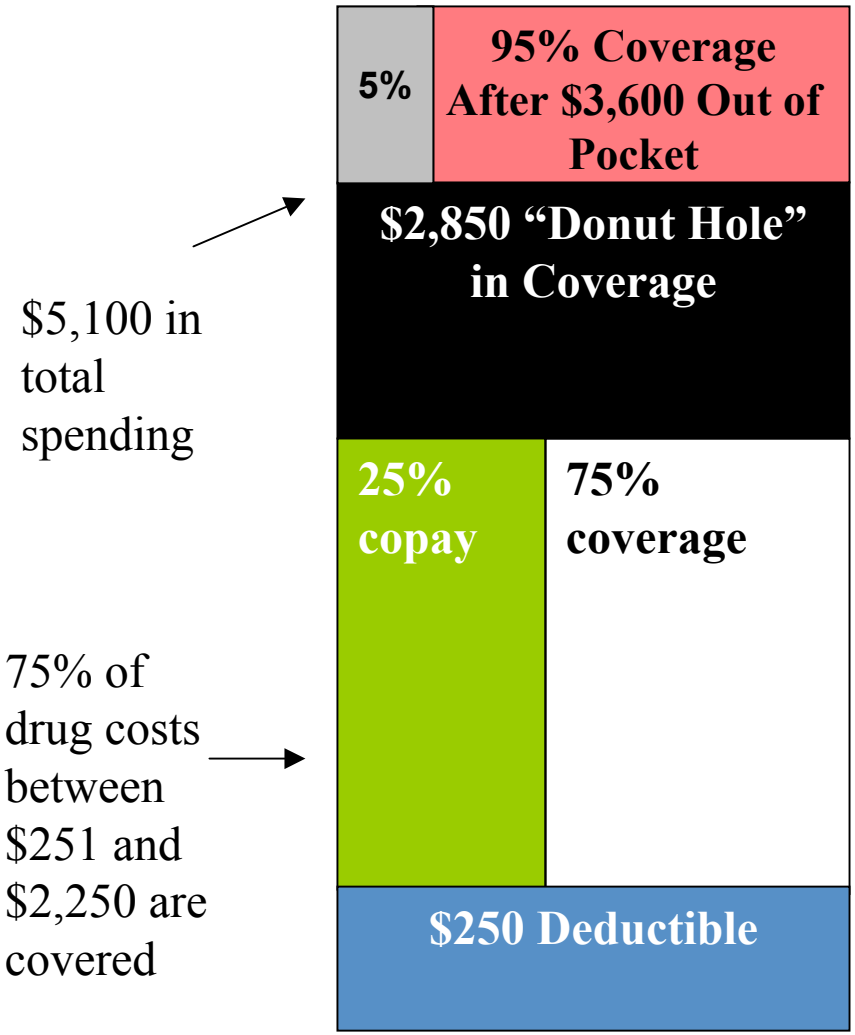
Drugs Covered

- Covers almost all types of prescription drugs and also medical supplies for injection of insulin. Excludes certain categories of drugs:
  - Weight loss and weight gain
  - Cosmetic purposes
  - Coughs and colds
  - Vitamins and minerals
- Drug plans may establish formularies and not cover all of the drugs in each class of drugs

Benefit Structure

- For federal budget reasons, they are significant gaps in coverage
  - $250 annual deductible
  - 25% copay from $251 to $2250 (subject to variation in individual plans)
  - no coverage from $2251 to $5100
  - 5% copay over $5100

Part D Benefit Package – 2006



Variable Copayments

- 25% copay is standard, but plans are allowed to establish variable copays so long as the total effect is financially equivalent
- Expectation is that the copay structure will look like typical private insurance
  - Small copay for generic drugs
  - Larger copay for preferred drugs for which the plan has negotiated discounts
  - Largest copay for other drugs

Negotiated Discounts

- Insurance plans will negotiate discounts with drug manufacturers for preferred drug status, as under current private drug coverage
- Discounts must be available to Medicare beneficiaries for drug purchases for which there is no Medicare coverage
  - $250 deductible
  - “Donut hole” from $2251 to $5100

Reaching the Catastrophic Limit

- How does a beneficiary reach the catastrophic limit?
  - Beneficiary out-of-pocket expenditures
    - First $250 is deductible – beneficiary pays
    - $251 to $2,250, beneficiary pays 25% ($500)
    - $2,251 to $5,100, beneficiary pays 100% ($2,850)
    - TOTAL out-of-pocket expenditures of $3,600
  - Drug plan expenditures
    - 75% from $251 to $2,250, or $1,500
  - Total drug spending of $5100
- Beneficiary also pays premium of $35/month ($420/year)

Summary of Drug Benefit

- The new benefit offers good coverage for moderate expenses (with a 25% copay)
- Also protects against very high drug bills
  - Pays only $1500 of first $5100 in yearly expenses
  - But 95% of drug expenses after that
- Individuals enrolled in the new benefit will also receive discounts even when they have to pay 100% of the drug cost
  - Discounts may be larger than the discounts available under the discount card in 2004-05

Premium Subsidies

- There will be no premium (normally $35/month) for certain beneficiaries
  - Medicaid recipients
  - Low income and assets
    - Individual: income $12,569, assets $6,000
    - Couple: income $16,862, assets $9,000
- Reduced premium for others
  - Individual: income $13,965, assets $10,000
  - Couple: income $18,736, assets $20,000

Subsidies to Other Low-Income Beneficiaries

- Individual: $12,569 income, $6,000 assets (135% FPL)
- Couple: $16,862 income, $9,000 assets
  - No deductible
  - Copay: $2 generics, $5 brand name drugs

- Individual: $13,964 income, $10,000 assets (150% FPL)
- Couple: $18,736 income, $20,000 assets
  - $50 deductible
  - 15% copay

Retiree Health Plans

- Employers receive 28% subsidy for retiree health plan drug costs between $250 and $5000 per individual

- Intended to encourage employers to maintain drug coverage for their retirees

Enrollment

- Open enrollment period is Nov. 15, 2005, through May 15, 2006
- Eligible individuals who fail to enroll at that time will be subject to penalties (increased premium) if they enroll later, unless they were covered by equivalent prescription drug coverage in the meanwhile
  - Retiree coverage may often be equivalent

Medigap Policies

- Currently, the more expensive Medigap policies include a prescription drug benefit
- After January 1, 2006, Medigap policies may not provide drug coverage

MSAs

Medical Savings Accounts

- Made permanent in legislation
- MSA plan combines high deductible ($1000-$6000) and catastrophic insurance coverage
- Medicare makes a payment into the account
  - Beneficiary can use funds to pay the high deductible
  - Funds can be used for healthcare expenses not covered by Medicare
  - Funds can also be used for nonmedical purposes (but are taxable)
  - Unused funds roll over to next year

DIFFERENCES IN ESTIMATED COSTS

Differences in Cost Estimates

- Congressional Budget Office estimated 10-year cost of legislation at $395 billion
- Medicare actuary estimated cost at $534 billion
- Reasons for difference were technical assumptions
  - Actuary assumed 32% of beneficiaries will enroll in Medicare Advantage plans, while CBO assumed 9%
  - CBO assumes slightly lower enrollment in new drug benefit and slightly lower drug costs per enrollee
  - CBO assumes slower use of subsidies for low-income individuals

Importation

- Why import drugs from abroad?
- [news stories]
- In the MMA, Congress permitted importation!…but with a string attached: the Secretary of HHS must certify safety and cost savings to American consumers

The origins of modern drug regulation

- Food, Drug and Cosmetic Act of 1938
- FDA role in pre-market approval of new drugs as safe and effective
- FDA oversight of production in U.S. and abroad
- Prescription Drug marketing Act (PDMA)

Good, bad and ugly

- Good: drugs manufactured in FDA-inspected facilities in U.S. or abroad and imported or re-imported by the manufacturer
- Bad: drugs manufactured in foreign facilities that make the U.S.-approved version but which may be different
- Ugly: drugs manufactured in foreign facilities that the FDA has not inspected

How big is the import business?

- 2003: 5 million shipments, comprising 12 million prescription drug products, valued at $700 million, entered the U.S. from Canada by internet sales and travel to Canada.
- Similar volume from the rest of the world

Task Force Report

- HHS Task Force's objections to liberalizing importation rules:
  - 1. The cost of extending the safety protections of the "closed system" to imports could be prohibitive
  - 2. There are significant risks associated with the ways individuals are currently importing drugs.

Task Force Report

- 3rd: "Personal" importation (Mom's solution) cannot be made safe.

- 4TH: The savings from imports won't offset the additional regulatory costs.

Task Force Report

- 5th: The savings on imports is overrated anyway.

- 6th: Importation may undermine innovation.

Task Force Report

- 7th: The effects of legalized importation on intellectual property are uncertain but like to prompt constitutional challenges and to be problematic for enforcement of IP rights and international trade agreements.
- Last: Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies etc.

California's Initiatives

- 2003: CA AG asks FDA for its views of importation by the state.

  [www.fda.gov/opacom/gonot.html]

Ask Arnold

- Can California do better in providing its citizens safe and affordable prescription drugs?
- Ask the “Girlie Men” or “The Three Stooges” or members of the Cauleefourneeuh Legislature who are just “hanging around” Sacramento.

Bills, bills, bills.

- Their answer: Numerous pieces of legislation focusing on access to safe, affordable prescription drugs have been introduced since the start of the new legislative session.

Drug Safety

- Assembly Bill 71 – (Frommer) Creates the Office of California Drug Safety Watch. Establishes toll-free number for reporting adverse drug reactions. Establishes a Web site to provide up to date information to the public about adverse drug reactions.

On behalf of the Makers of Vioxx…

- Assembly Bill 72 – (Frommer)
- Requires prescription drug manufacturers furnishing prescription drugs in California to report to the Department of Health Services health studies that have been or are being conducted by or on behalf of the manufacturer.

Web Site Program

- Assembly Bill 73 – (Frommer)
- Creates the California Rx Prescription Drug Web Site Program. Web site would offer California residents information on obtaining prescription drugs at affordable prices. International pharmacies may be assessed a fee to be evaluated by the Department of Health and Human Services and, if approved, included as a source of affordable prescription drugs.

The Hotline

- Assembly Bill 74 – (Frommer)

  Creates Rx Prescription Drug Hotline to provide consumers and health care providers information on obtaining prescription drugs at affordable prices. Can charge a fee of up to 50 cents per phone call.

California Rx Plus State Pharmacy Assistance Program

- Assembly Bill 75 – (Frommer)
- Establishes the California Rx Plus State Pharmacy Assistance Program to be administered by the California Department of Health and Human Services Would negotiate rates for and provide prescription drugs at a discount to qualified California residents who do not receive prescription drug benefits through Medi-Cal or Healthy Families.

One Big Buyer

- Assembly Bill 76 – (Frommer)
- Establishes within the California Department of Health and Human Services the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies.

Extending Discounts to Correctional Facilities

Assembly Bill 77 – (Frommer)
Extends cost-cutting activities to saving money on prescription drugs in correctional facilities

Regulating PBMs

- Assembly Bill 78 – (Pavley)
- Defines “Pharmacy Benefits Management”- An entity that performs pharmacy benefits management.
- Requires certain disclosures to the purchaser, including the PBM’s revenues and its drug formularies.
- Effort to increase regulatory oversight of PBMs

Down the Road….

With the advent of Medical Savings Accounts, an increase “rush to regulate.”

Expansion of discounts being offered for health care services and products.

Need to Amend California Law

- Business and Professions Code Section 650 (prohibiting the offer of a discount in exchange for referrals by health care providers licensed under B&P Code Division 2) and
- Health and Safety Code Section 445 (prohibiting referral programs to health care providers, both individuals and facilities)

Consumer Protection

- Need to determine what is “base cost” upon which a bona fide discount is offered.
- Also, avoid “silent PPOs” where provider agrees to participate in one discount plan and finds out he or she is on a list that has been “sold” to another discount provider.

Future Fun

- Prior Legislative efforts have failed.
- Department of Managed Health Care losing the race to NOT be the regulatory agency charged with regulation of discount plans.
- Monitor developments by logging on to California Legislature web site www.leginfo.ca.gov